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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,404	09/08/2003	Gavin William Halbert	031749/268956	3177

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,404

Applicant(s)

HALBERT ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-14 is/are rejected.
- 7) ☒ Claim(s) 3-6 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
2. Applicant's response to the Office Action mailed February 11, 2005, on September 30, 2005, is acknowledged.

***Claim Disposition***

3. Claims 1-25 are pending. Claims 1-15 are under examination.

***Withdrawn-Specification Objections***

4. Previous objection to the Specification and Oath are withdrawn by virtue of submission of an amendment.

***Withdrawn-Objection to Claims***

5. Previous objection to claims are withdrawn by virtue of submission of an amendment.

***Withdrawn-Claim Rejections - 35 USC § 112***

6. Previous rejections to claims are withdrawn by virtue of submission of an amendment.

***Withdrawn-Claim Rejections - 35 USC § 112***

7. Previous rejections of the claims under 35 U.S.C. 103, Obvious-type Double Patenting is withdrawn by virtue of submission of a Terminal Disclaimer.

***New-Claim Objection***

8. Claims 3-6 and 15 is objected to because of the following informalities:

- (a) Claims 3-7 and 12-14 are objected to as depending from a rejected based claim.
- (b) For clarity and precision of claim language, it is suggested that claim 15 is amended to recite "The particle according to claim 1", in lieu of "A particle according to claim 1".

Correction is required.

***Maintained and Amended-Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2 and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundberg et al. (Biochim. Biophys. Acta, vol. 1149, pages 305-312, 1993).

Lundberg teach a non-naturally occurring receptor competent LDL particle comprising a peptide component (apolipoprotein B) wherein the peptide component has a binding site for an Apo B protein receptor and a lipophilic substituent (claim 1, see abstract). Further, NH<sub>3</sub><sup>+</sup> at the

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amino terminus and COO- at the carboxy terminus inherently bonds via ionic bonding to the lipophilic substituent due to the charged nature (claim 1). In addition, the lipophilic substituent contains cholesterol (claims 7-9 see abstract). Further, the presence of hydroxyl, carboxyl, and amino groups is inherent in the amino acids which make up peptides, thus the limitations of claim 10 is met. Since the peptide component of the particle is apolipoprotein B, it is inherent that the peptide has 100% amino acid identity to an Apo B protein binding sequence (claims 11-13) and would inherently possess the structure recited in claim 14. Thus, the reference anticipates the claimed invention.

### ***Response to Arguments***

10. The response filed on September 30, 2005 has been considered, however, is not fully persuasive. Note that the rejection under 35 U.S.C. 102 remains for the reasons of record and set forth herein. The response on page 10 states that the Lundberg et al. reference does not teach a peptide component bonded at the amino and/or carboxy terminus thereof. Further it is stated that Lundberg et al. procedure does not lead to Apo B bonded at the N or C terminus (page 11). This argument is not persuasive as the abstract of the Lundberg et al. reference disclose that mixed phospholipids/cholesterol liposomes were conjugated with native and acetylated Apo B, the protein part of low density lipoprotein (LDL). The mere fact that a conjugate is taught means a bond exists. The limitation of the N and/or C terminus is inherent as a bond would exist at minimally one of those ends and based on the charged nature of the N or C terminus. Further the liposome in the Lundberg et al. reference comprise cholesterol (lipophilic substituent). Thus, the rejection remains.

*Conclusion*

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Patent Examiner

*12/20/05*

**HOPE ROBINSON  
PATENT EXAMINER**